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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/628,186	07/28/2000	Paul Chinn	P 037003 0280721	2673

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Robin L. Teskin
Shaw Pittman
2300 N Street, N. W.
Washington, DC 20037-1128

EXAMINER
SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
1644	11

DATE MAILED: 10/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
628,186	CHINN
Examiner	**Group Art Unit**
SAUNDERS	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1-19 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 1-19 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). 9

☑ Notice of Reference(s) Cited, PTO-892

☑ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other _____

Office Action Summary

The preliminary amendment of 7/28/00 has been entered. Claims 1-19 are pending and under examination.

The disclosure is objected to because of the following informalities: at page 14, line 3, the reference to two copending applications is incomplete.

Appropriate correction is required.

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 3, recitation of "ligand" is confusing. Assuming this is modified by "the", it lacks antecedent basis and is referenced no where else in the claim.

In claim 1, lines 7-8, "the radiolabelled antibody" lacks antecedent basis.

In claim 18 "70%" is unclear as to what it is relative to -- i.e. what binding specificity is 100%?

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-5, 8, 10-14 and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Mather et al. (Eur. Jour. Nucl Med., 15, 307, 1989).

Mather et al. label chelator conjugated monoclonal antibodies with Yttrium-90, without conducting post-labeling purification of the radiolabeled antibodies. These preparations are taught as suitable for administration to patients. In instant claim 1, recitation of "sufficient purity, specific activity, and binding specificity" are qualitative terms, the meaning of which can vary with the nature of the isotope, the antibody, the condition of the patient, and the amount of time that elapses between radiolabelling and administration. As such these terms offer no patentable weight over the prior art.

Regarding claim 8, note that Mather et al. teach the chelator is DTPA which is properly considered as a "derivative" of MX-DTPA, phenyl-DTPA, benzyl - DTPA, or CHX - DTPA.

With respect to the temperature pH and buffering conditions recited in claims 10-14, note page 308, column 1 teaching room temperature and page 309, column 2 teaching 0.1M acetate buffer at pH 5.5-6.5.

For claim 17, note abstract and page 311, col. 2 teaching a labeling efficiency greater than 95%.

With respect to claim 18, note paragraph spanning pages 309-310 teaching relative immunoreactivities, measured at 24 hrs., of 74% and 90%, depending upon the specific activity of the radiolabelled preparation. Applicant's recitation of "at least about 70% in claim 18, fails to state what this is compared to as a 100% standard. The claim fails to state anything about the timing of determining the binding specificity following the labeling reaction. As such rejection over the reference is proper.

Claims 1, 8, 10-14 and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Richardson et al. (Nucl. Med Commun. 8,347,1987).

Richardson et al. teach radiolabelling of DTPA conjugated antibodies with Indium - 111. No post labeling purification is required (page 354, first full para.). It is noted that the reference teaches an isotope used for in vivo imaging, rather than therapy. It is also noted that claim 1 only recites "therapeutic" in the preamble, and that step (I) simply recites "the radioisotope". Claim 1 is properly anticipated because limitations recited only in the preamble are given no weight.

Claim 8 is rejected with the same rational stated for Mather et al.

Regarding the temperature, pH and buffer conditions of claims 10-14, note acetate buffered saline solution taught in Table 1. Room temperature labeling is deemed inherent, since the disclosure is directed to the use of the taught kits and methods by nonspecialists in nuclear medicine.

Regarding claims 17-18, note Figures 1 and 2.

Claims 1-5, 8, 10-11 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Chinol et al. (Jour. Nucl. Med., 28,1465,1987) in light of Hnatowich et al. (Jour. Imm. Meth. 65,147, 1983).

Chinol et al. teach yttrium-90 radiolabelling of DPTA conjugated antibodies. The taught method is developed for the avoidance of post labeling purification (para. spanning pages 1469-1470). HPLC steps conducted after labeling are for the purpose of analysis of radiochemical purity, not for preparing an administrateable product. (Page 1467, col. 1, second full para.). Thus the claims are anticipated.

Regarding claims 10-11, room temperature is considered inherent to the disclosure of Chinol et al. See method for indium-III labeling of DPTA-conjugated antibodies of Hnatowich et al., which is referenced by Chinol et al. at page 1467, col. 1.

Regarding claim 17, note page 1470, col. 1, second full paragraph.

Claims 1-3, 5, 17 and 19 are rejected under 35 U.S.C. 102(b) or (e) as being anticipated by Ultee et al. (WO 96/14879, cited in form 1449 or U.S. 5,942,210, cited on form 892).

The disclosures of the WO and U.S. references are equivalent. For convenience the examiner will refer to the US document by col. and line numbers.

Ultee et al. disclose a "one pot" method for radiolabelling a lyophilized preparation of a chelate conjugated antibody. See especially col. 16, line 66 - col. 17, line 9; col. 17, line 62 - col. 18, line 7; col. 19, lines 43-60; col. 20, lines 57-63; col. 30, lines 11-19; col. 31, lines 35-53.

Note that the "linker molecule" of Ultee et al. is the equivalent of the instant chelator (see col. 14, line 21 - col. 16, line 32). In the above noted portions there is no teaching of any separation step following radiolabelling. Furthermore it is clear that Ultee et al. intended to directly administer the radiolabelled antibody from the reaction put to a subject, since they tested the toxicity of tricine (a component of the lyophilized mixture) in mice. See col. 29, line 43 - 62.

It is to be noted that while all examples show Tc-99 (an imaging radioisotope), Ultee et al. clearly teach like methods for preparing antibodies radiolabelled with Re-186 or Re-188 (therapeutic radioisotopes). See col. 2, lines 59-60; col. 9, lines 40-42; col. 18, lines 1-3. Thus claim 1 is anticipated. Also, as with Richardson et al., use of Tc anticipates claim 1.

Regarding limitations of dependent claims 2-3, Re isotopes inherently meet the limitations of these claims (see instant specification page 10).

With respect to claims 5 and 19 note teachings of incorporation of 50-200 mCi/mg in less than five minutes (col. 21, lines 33-36).

Regarding claim 17, note teachings of 95% incorporation in 5 minutes. See col. 20, lines 61-63; col. 21, lines 6-7.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

October 8, 2002

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644